3M[™] Attest[™] Auto-reader 390G



- (GB) Operator's Manual
- (FR) Manuel de l'utilisateur
- **DE** Benutzerhandbuch
- (IT) Manuale dell'operatore
- (ES) Manual del usuario
- (ES) Manual del operador
- N Bedieningshandleiding
- SE Användarhandbok
- **DK** Brugsvejledning
- NO Brukerhåndbok
- (FI) Käyttöopas

- (PT) Manual do Utilizador
- (PT) Manual do Operador
- GB Εγχειρίδιο Χειριστή
- Instrukcja obsługi
- CZ Příručka pro obsluhu
- (SI) Priročnik za uporabo
- (RU) Инструкция по эксплуатации
- (HB) Upute za korištenje
- (TR) Operatör Kılavuzu
- CN 操作指南
- 🖽 คู่มือปฏิบัติงาน
- (KR) 작업자 매뉴얼



Read and understand all safety information before using this product.

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GB

PREFACE

Manual Revision History

| Date | Revision Reason For Revision | |
|---------------|------------------------------|---|
| November 2012 | А | Initial Issue |
| February 2013 | В | To clarify, in the Indications for Use section, that Attest [™] 1294 Biological Indicators are used to monitor the ethylene oxide sterilization process. |
| July 2013 | С | To revise: the Warranty statement; and the WEEE symbol and associated explanatory text. |

Content Disclaimers

Pictorial Disclaimer

Sample printouts, graphics, displays and screens are for information and illustration purposes only, and shall not be used for clinical or maintenance evaluations. Data shown in sample printouts and screens do not reflect actual patient names or test results.

Hardware Disclaimer

The 3M[™] Attest[™] Auto-reader 390G hardware specifications are subject to change. The system images, hardware components and hardware specifications included in the manual may not match the system installed. Any changes or modifications to the authorized system installation have been verified as compatible with the functionality outlined in this document.

INDICATIONS FOR USE

The 3MTM AttestTM Auto-reader 390G is designed to incubate and automatically read the 3MTM AttestTM Rapid Readout Biological Indicator for Ethylene Oxide, 1294, at 37°C for a final fluorescent result at 4 hours.

WARRANTY

The 3M[™] Attest[™] Auto-reader 390G has a one year limited product warranty. The US warranty, remedy and limitations are described in the Price Quote form and in the Direct Price Pages. For countries outside of the US, any warranty is established by the subsidiary with responsibility for service of the 3M[™] Attest[™] Auto-reader 390G.

Serial Number

For easy identification, each 3M[™] Attest[™] Auto-reader 390G has a unique serial number printed on a label found on the back of the unit and displayed on the left side of the upper

row of text on the LCD Display when the user depresses the ¹⁰⁰ button. Please record your serial number in this manual for future reference: ______.

SAFETY AND PRECAUTIONS

The 3M[™] Attest[™] Auto-reader 390G and its related devices and accessories are designed to provide safe and reliable service when used according to the instructions provided. Please read, understand, and follow all safety information contained in the instructions for use included with the 3M[™] Attest[™] Auto-reader 390G and 1294 Rapid Readout Biological Indicator devices prior to use. Use this equipment only for the purpose described in this Operator's Manual. **Retain these instructions for future reference.**

The unit is designed to be used only with the Power Supply module and Ethernet cable supplied by 3M. If this product is used in a manner not specified, the protection provided by the product may be impaired.

Explanation of Single Word Consequences



Warning: Indicates a hazardous situation, which, if not avoided, could result in death or serious injury.



Caution: Indicates a hazardous situation, which, if not avoided, could result in minor or moderate injury.

Warnings and Safety Precautions

The following warnings and precautions should be followed to avoid unsafe actions that could result in personal injury or damage to the instrument.

WARNING: To reduce the risk associated with hazardous voltage

Use indoors only.

Do not use the equipment if it is not working properly or if it has suffered any damage.

Use only the power supply specified for this product and certified for the country of use.

CAUTION: To reduce the risk of injury or instrument damage

Do not spill liquid onto or into the instrument. Do not immerse the unit in liquid.

Always unplug the 3M[™] Attest[™] Auto-reader 390G and allow to cool before cleaning.

Clean external surfaces using only the instructions provided by the manufacturer.

Do not open the instrument housing - there are no user serviceable parts.

The instrument must be returned to the manufacturer for repair.

Allow the 3M[™] Attest[™] Rapid Readout Biological Indicator to cool for the recommended time period before activating. Activating or excessive handling of the biological indicator before cooling may cause the glass ampoule to burst.

Wear safety glasses when activating the $3M^{\mbox{\scriptsize TM}}$ Attest $^{\mbox{\scriptsize TM}}$ Rapid Readout Biological Indicator.

WARNING: To reduce the risk associated with incorrect results

Instrument is to be used by operators familiar with the device, device functionality, and Operator's Manual.

Do not place the instrument in environment exposed to sunlight or strong incandescent light.

Do not place instrument close to any device that emits a strong electro-magnetic field.

Do not use on a vibrating surface.

Match the cap color of the 3M[™] Attest[™] Rapid Readout Biological Indicator with the color-coded configuration sticker surrounding the 3M[™] Attest[™] Auto-reader 390G incubation wells.

Do not remove or change placement of 3M[™] Attest[™] Rapid Readout Biological Indicator once it is placed into a well.

Do not remove the $3M^{TM}$ AttestTM Rapid Readout Biological Indicator from the incubation well until the (+) or (-) symbol on the LCD panel indicates the test is complete.

Caution: To reduce the risk associated with incorrect results

To avoid the possibility of the 3M[™] Attest[™] Rapid Readout Biological Indicator vial absorbing fluorescent residue from a chemical indicator or tape, place the 3M[™] Attest[™] Rapid Readout Biological Indicator vial so it does not come in direct contact with chemical indicators or tape.

HEALTH AND SAFETY INFORMATION

Device Safety Compliance

The $3M^{TM}$ AttestTM Auto-reader 390G complies with the following standards as demonstrated by the CB Scheme Certificate and test report issued by Underwriters Laboratories (UL):

- IEC 61010-1 (2001) Second Edition. Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
- IEC 61010-2-010 (2003) Second Edition. Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials

The 3MTM AttestTM Auto-reader 390G is listed as Laboratory equipment and carries the UL mark with adjacent indicators "C" and "US" based on compliance to the standards UL 61010-1 and CAN/CSA 22.2 No. 61010-1.

The $3M^{TM}$ AttestTM Auto-reader 390G complies with the CE mark related to the Low Voltage Directive (LVD) 2006/95/EC as confirmed in the Declaration of Conformity.

The 3M[™] Attest[™] Auto-reader 390G complies with the RoHS Directive, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The 3M[™] Attest[™] Auto-reader 390G complies with the WEEE Directive, Directive 2012/19/EU of the European Parliament and of the Council of 04 July 2012 on waste electrical and electronic equipment (WEEE).

EMC Compliance

The $3M^{TM}$ AttestTM Auto-reader 390G complies with the following EMC standards as confirmed in the Certificate of Compliance generated by 3M:

IEC 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

The 3MTM AttestTM Auto-reader 390G complies with the EMC requirements of the CE mark EMC Directive 2004/108/EC.

The 3M[™] Attest[™] Auto-reader 390G complies with the Australian and New Zealand electrical safety and electromagnetic compatibility requirements as confirmed in the Supplier's Declaration of Conformity that is linked to the Australian/New Zealand RCM (Regulatory Compliance Mark).

Note: This equipment has been tested and found to comply with the limits for a Class A digital device pursuant to Part 15, Subpart B, of the FCC Rules. These limits are designed to provide a reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their own expense.

This Class A digital device meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Class 1 LED Product

An investigation was conducted on the 3M[™] Attest[™] Auto-reader 390G per the requirements of IEC 60825-1 Ed. 1.2 (A2:2001). The 3M[™] Attest[™] Auto-reader 390G is a Class 1 LED product with Class 1 Internal Radiation.

The LED apertures are located at the bottom of each Incubator/Reader well perpendicular to the opening of each well.

NOTE: Class 1 products are safe for unprotected exposure of the eyes.

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Note: The use of the term "controls" in the above caution statement as required by IEC 60825-1 Ed. 1.2 (A2:2001) refers to mechanisms by which the 3M[™] Attest[™] Auto-reader 390G may be controlled and not to the use of biological indicator controls.

EXPLANATION OF PRODUCT AND PACKAGING LABEL SYMBOLS

Attention - Refer to the instructions for use

Waste Electrical and Electronic Equipment (WEEE) and EU Battery Directive. This symbol indicates that both the device and the lithium ion battery contained therein need to be disposed of properly.



UL Listed to US and Canadian Safety Standards Mark of Conformity to European Directives



Direct current



Compliant to all applicable ACMA regulatory arrangements (RCM)

| Manufacturer |
|--------------|
|--------------|

REF Catalog number

EC REP Authorized representative for the European Community

SN Serial number

● 1294 √

The 3MTM AttestTM Auto-reader 390G is **not** designed to incubate 3MTM AttestTM 1264 EO Biological Indicators, which have a sterilant entry port in the center of the top of the cap. The 3MTM AttestTM Auto-reader 390G is designed to incubate and read only 3MTM AttestTM Rapid Readout Biological Indicators for EO, catalog number 1294. Other biological indicators (BIs) are not compatible with this device and cannot be used.



GB

SPECIFICATIONS

Power Supply Specifications

| Power supply Voltage Range | Operating Condition 100-240 | Units Volts AC |
|--------------------------------------|---------------------------------------|--------------------------|
| Frequency | 50/60 | Hertz |
| Current | 0.6 | Amps |

Environmental Operating Conditions

| Environmental Condition Altitude | Operating Condition 3000 (max) | Units Meters |
|-------------------------------------|--|------------------------|
| Operating Temperature | 16 – 29 | °C |
| Storage Temperature | -10 to 50 | °C |
| Operating Relative Humidity | 20-80 (non-condensing) | % |
| Voltage Range | 12 | Volts DC |
| Frequency | DC | |
| Current | 1.2 | Amps |
| Installation/Over Voltage | Category II | |
| Pollution Degree | 2 | |

INSTRUCTIONS FOR USE – Initial Set-up

Choose Location

Place 3M[™] Attest[™] Auto-reader 390G on a firm and level surface, away from sunlight and incandescent light. To save counter space, units may be stacked two high.

WARNING:

the country of use.

Do not place the instrument in environment exposed to sunlight or strong incandescent light.

WARNING: Use only the power supply specified for this product and certified for

- Do not place instrument close to any device that emits a strong electro-magnetic field.
- Do not use on a vibrating surface.

Select & Install Correct Power Plug

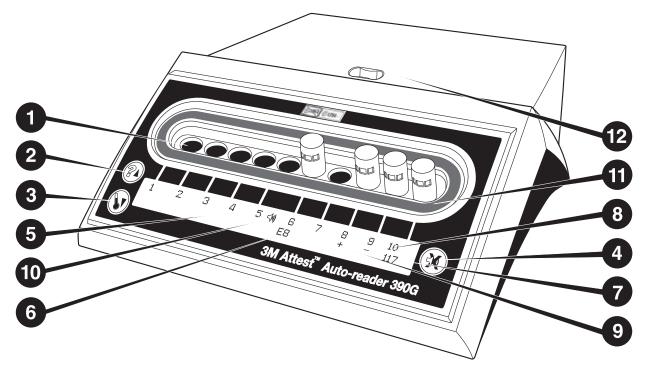
The 3MTM AttestTM Auto-reader 390G power supply comes with multiple blade configurations. Install the blade configuration appropriate for your country into the power supply and plug into appropriate AC grounded outlet.

Wait 30 Minutes Before Using

Once plugged in, allow a 30 minute warm-up period before placing 3MTM AttestTM Rapid Readout Biological Indicators into the incubation wells. The C1 caution code will disappear when proper incubation temperature is reached.

Special Considerations

It is recommended that the unit be left on to eliminate warm-up periods. The unit may be turned off when it is anticipated that it will not be used for an extended period.



Please familiarize yourself with the face of the 3M[™] Attest[™] Auto-reader 390G:

Wells

1. Incubation/Reader Wells – The 3M[™] Attest[™] Auto-reader 390G has ten incubation wells.

Buttons

2. Information / Up Arrow Button

- 4. Buzzer Alarm OFF / Enter Button

3. Temperature / Down Arrow Button

Information Display

- 5. LCD Display Display is backlit
- 6. LCD Display Example of Error Message for well #6
- 7. LCD Display Example of Remaining Incubation Time, in minutes, for well #10
- 8. LCD Display Example of Negative () BI result for well #9
- 9. LCD Display Example of Positive (+) BI result for well #8
- 10. LCD Display Alarm Enabled Indicator

Color-Coded Configuration Indicator

11. Incubation well configuration sticker is color-coded green

BI Crusher

12. BI Crusher Well

INSTRUCTIONS FOR USE – 3M[™] Attest[™] Auto-reader 390G Configuration

Note: Ideally, the 3M[™] Attest[™] Auto-reader 390G should be empty (i.e., have no incubating BIs) when it is reconfigured.

Press the ⁽²⁾ and ⁽³⁾ buttons on the front of the 3M[™] Attest[™] Auto-reader 390G simultaneously for 3 seconds to enter configuration mode. Once in configuration mode,

use the Up 🧼 and W Down buttons to set the 3M[™] Attest[™] Auto-reader 390G

clock and audible alarm as desired. The I button acts as an "Enter" key and moves the flashing cursor to the next changeable setting.

Setting the 3M[™] Attest[™] Auto-reader 390G Clock

The 3M[™] Attest[™] Auto-reader 390G date and time are displayed in this format: YYYY-MM-DD HH:MM, with the time displayed using a 24 hour clock. To change the year,

if necessary, push the up or down buttons to set desired year, then press to advance

to the month, adjust as necessary and press to advance to the day. Use the button to move to the time and set the hours and minutes.

Setting the Audible Alarm Function

Move across the top row of text by pushing the ^(W) button. The flashing "B" in Buzzer indicates this is a changeable setting. It is recommended this be set at "Buzzer Enabled" to audibly alert the operator to a positive BI but it may be set to "Buzzer Disabled" by using either the up or down button. Note: If Buzzer Disabled is selected, and the changes accepted, the speaker icon (*€*) will disappear from the LCD panel and the alarm will be disabled for all positive 3MTM AttestTM Rapid Readout Biological Indicators, error codes, and caution code alarm warnings. Note: The 3MTM AttestTM Auto-reader 390G display backlight flashes whenever an audible alarm sounds. Disabling the audible alarm does NOT disable the LCD display backlight flashing.

Press 🚳 to select the desired option and advance to the Accept screen.

Accept Screen

Use the up or down buttons to toggle between Yes and No, press it accept changes (Yes selected) or retain current settings (No selected) and exit the configuration mode. The LCD panel will return to the standard display.

INSTRUCTIONS FOR USE - Readout Procedure

Instructions for Biological Indicator (BI) Activation and Incubation

CAUTION: To avoid the possibility of the 3M[™] Attest[™] Rapid Readout Biological Indicator vial absorbing fluorescent residue from a chemical indicator or tape, place the 3M[™] Attest[™] Rapid Readout Biological Indicator vial so it does not come in direct contact with chemical indicators or tape.

WARNING: Match the green cap color of the 3M[™] Attest[™] 1294 Rapid Readout Biological Indicator with the green color-coded configuration sticker surrounding the 3M[™] Attest[™] Auto-reader 390G incubation wells.

CAUTION: Wear safety glasses when activating 3M[™] Attest[™] Rapid Readout Biological Indicators.

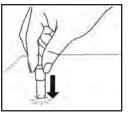
Follow this procedure for every 3M[™] Attest[™] 1294 Rapid Readout Biological Indicator to be read.



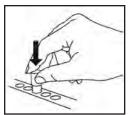
While wearing safety glasses, **CLOSE** the cap of the cooled 3M[™] Attest[™] 1294 Rapid Readout Biological Indicator (BI) by pushing cap down.



CRUSH the glass media ampoule in the Crusher Well built into the top of the 390G Auto-reader.



Holding BI by the cap, **TAP** the bottom of the vial on a tabletop until media wets spore strip at bottom of vial. Do not tap BI on Auto-reader.



PLACE the crushed BI in **color-coded** incubation well. Observe 3M[™] Attest[™] Auto-reader 390G LCD panel to confirm correct placement of the BI. If the BI is correctly seated, the 3M[™] Attest[™] Auto-reader 390G LCD panel will display ***, **, * and then 240 remaining minutes of incubation directly below the incubating BI. **RECORD** BI result.

WARNING: Do not remove the 3MTM AttestTM 1294 Rapid Readout Biological Indicator from the incubation well until the (+) or (-) symbol on the LCD panel indicates the test is complete.

INSTRUCTIONS FOR USE – Additional Information

BI Placement

Remaining incubation time, in minutes, will be displayed on the LCD display to indicate the 3M[™] Attest[™] Rapid Readout Biological Indicator is incubating in the reader well and should **not** be touched. The time remaining display indicates the results are not available and incubation is in progress.

Do not remove 3M[™] Attest[™] Rapid Readout Biological Indicator until the (+) or (-) symbol on the LCD panel indicates the test is complete.

Note: If 3M[™] Attest[™] Rapid Readout Biological Indicator is inadvertently removed before the incubation period is complete, an alarm will sound and a C2 Caution code will be displayed on the LCD panel under that well. You <u>must</u> return the 3M[™] Attest[™] Rapid Readout Biological Indicator to the reader well within 10 seconds or the results will be lost.

WARNING: Do not remove or change placement of 3M[™] Attest[™] Rapid Readout Biological Indicator once it is placed into a well. Doing so may result in loss of results and the 3M[™] Attest[™] Rapid Readout Biological Indicator test may be invalid.

INSTRUCTIONS FOR USE – Positive Control

Positive Control

Activate and incubate at least one non-processed 3M[™] Attest[™] 1294 Rapid Readout Biological Indicator to use as the positive control each day that a processed 3M[™] Attest[™] 1294 Rapid Readout Biological Indicator is incubated and read by the unit. Write a "C" (for "control") and the date on the label. The positive control can be placed in any incubation well. The positive control should be the same part number and have the same lot number as the processed 3M[™] Attest[™] Rapid Readout Biological Indicator in the unit.

The positive control biological indicator helps confirm:

- correct incubation temperatures are met (heater block reading of 37°C +/-2°C);
- viability of spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals;
- · capability of media to promote rapid growth; and
- proper functioning of 3M[™] Attest[™] Auto-reader 390G components.

INSTRUCTIONS FOR USE – Interpretation of Results

Fluorescent Results

After placing a 3M[™] Attest[™] Rapid Readout Biological Indicator into an incubation well, the 3M[™] Attest[™] Auto-reader 390G LCD panel will display ***, **, * and then the remaining minutes of incubation directly below the incubating BI to indicate that incubation/reading is in progress.

A (+) will display on the LCD panel directly under the BI and an alarm will sound (if the sound feature is enabled) as soon as a positive 3M[™] Attest[™] Rapid Readout Biological Indicator result is detected.

At the end of the four hour incubation time, if a negative 3M[™] Attest[™] Rapid Readout Biological Indicator result is detected, a (-) will display on the LCD panel directly under the incubating Bl. The final negative fluorescent result (-) for a processed 3M[™] Attest[™] 1294 Rapid Readout Biological Indicator after 4 hours of incubation indicates an acceptable sterilization process. The positive control should read positive (+).

After either the + or − symbol is displayed, and the result is recorded, the 3MTM AttestTM Rapid Readout Biological Indicator can be removed from the well. The 3MTM AttestTM Rapid Readout Biological Indicator should not be removed or touched when the display indicates remaining incubation time.

The positive (unprocessed) control 3M[™] Attest[™] 1294 Rapid Readout Biological Indicator must provide a positive fluorescent result (+). Processed 3M[™] Attest[™] Rapid Readout Biological Indicator results are not valid until the positive control reads fluorescent positive (+). With a processed 3M[™] Attest[™] Rapid Readout Biological Indicator, a positive (+) result indicates a sterilization process failure.

Act on any positive test results immediately. Determine the cause of the positive 3M[™] Attest[™] Rapid Readout Biological Indicator and retest the sterilizer following current facility policies and procedures.

Optional Visual pH Color Change Result

3M[™] Attest[™] 1294 Rapid Readout Biological Indicators may be further incubated for a visual pH color change. Due to the high sensitivity of the fluorescent result, there is no advantage to incubating the 3M[™] Attest[™] 1294 Rapid Readout Biological Indicators beyond 4 hours. This optional further incubation is not intended for routine use but may be used for special studies. A humidified incubator will be required to avoid media dry out. In the case of a positive control BI, a yellow color change of the growth media will appear within 7 days. Any observation of a yellow color within the vial indicates a positive result. The pH color change result can be recorded and the BI discarded as soon as the yellow color is observed and the result recorded. In the case of a processed BI, a media color change from blue-green to yellow indicates a sterilization process failure. A negative pH color change result, i.e., media remains blue-green, can be assessed at 7 days.

INSTRUCTIONS FOR USE – Disposal

Instrument contains a lithium battery. Dispose of instrument in accordance with federal, state, and local requirements.

FEATURES OF THE 3M™ ATTEST™ AUTO-READER 390G

Audible Alarm

An audible alarm will sound, the LCD display backlight will flash, and a (+) symbol will be displayed on the LCD panel directly under the incubating BI when a positive result is detected. An alarm will also sound if a 3M[™] Attest[™] Rapid Readout Biological Indicator is removed from the 3M[™] Attest[™] Auto-reader 390G well before a final result has been detected. Data will be lost if the 3M[™] Attest[™] Rapid Readout Biological Indicator is not replaced in the incubation well within 10 seconds.

Alarm On/Off 🔯

The audible alarm for positive results can be turned off for a particular 3M[™] Attest[™] Rapid Readout Biological Indicator. This is accomplished by pressing the "Buzzer Alarm OFF" button after the alarm has sounded. This will turn off the alarm for that Bl only. Any positive 3M[™] Attest[™] Rapid Readout Biological Indicator results subsequently detected in other wells will result in the alarm sounding. Removing the 3M[™] Attest[™] Rapid Readout Biological Indicator will reactivate the alarm for that well. Pressing the "Buzzer Alarm OFF" button will not silence the alarm for error or caution code alarm warnings. To disable the alarm, see configuration section.

Stackable

To save counter space, 3M[™] Attest[™] Auto-reader 390Gs may be stacked two high.

Information Button

When the Information button is pressed once the 3M[™] Attest[™] Auto-reader 390G displays two lines of text in the LCD display.

The top row indicates (left to right):

- 3M[™] Attest[™] Auto-reader 390G serial number
- 3M[™] Attest[™] Auto-reader 390G embedded software version (V X.Y.Z)
- Current date and time.

The bottom row indicates (left to right):

- The BI type configuration for wells 1-5.
- The BI type configuration for wells 6-10.

Press the information button twice and the 3M[™] Attest[™] Auto-reader 390G LCD panel will display two additional lines of text.

The top row indicates:

Dynamic IP address (if unit is connected to an Ethernet jack).

The bottom row indicates (left to right):

 Date (YYYY-MM-DD) and time that power was supplied to the 3M[™] Attest[™] Auto-reader 390G.

Temperature Monitoring W

The 3MTM AttestTM Auto-reader 390G contains an internal temperature self-diagnostic program. Should the temperature fall outside the specified range (37°C +/-2°C) an error code will be displayed. The heater block temperature may be checked by depressing the Temperature button once.

Easy Configuration

The 3M[™] Attest[™] Auto-reader 390G may be configured using either the buttons located on the front of the unit or using the optional 3M[™] Attest[™] Auto-reader 390G Web App.

Optional 3M[™] Attest[™] Auto-reader 390G Web App

If desired, the 3M[™] Attest[™] Auto-reader 390G may be connected to a PC via an Ethernet connection for additional capabilities:

- Remotely view current status of BIs in the 3M[™] Attest[™] Auto-reader 390G via PC or mobile hand held devices. For full functionality, the use of an HTML5 compliant browser with JavaScript enabled is recommended.
- Remotely view and configure 3M[™] Attest[™] Auto-reader 390G settings.
- View the last 100 BI records.
- Print out documentation using a local or networked printer and/or save documentation as an electronic file.*

Note: To access the 3M[™] Attest[™] Auto-reader 390G Web App within a secure network, the PC or mobile device must have access to the secure network; options include connecting via a network Ethernet cable, signing in to the facility's wireless network, or connecting via a virtual private network (VPN).

* Refer to your facility's record keeping policy and procedure.

CARE AND CLEANING

CAUTION: Always unplug the $3M^{TM}$ AttestTM Auto-reader 390G and allow to cool before cleaning.

Do not spill liquid onto or into the instrument. Do not immerse the unit in liquid.

Clean external surfaces using only the instructions provided by the manufacturer.

The instrument must be returned to the manufacturer for repair.

Clean the exterior surface of the 3M[™] Attest[™] Auto-reader 390G by wiping it with a damp cloth moistened with a mild detergent. Do not attempt to clean interior components. If additional cleaning of the wells is required, call for repair or replacement.

Note: The 3M[™] Attest[™] Auto-reader 390G does not contain any user serviceable parts or require any routine maintenance. Any malfunctions will be indicated by an error code. Refer to the Troubleshooting Guide section for error code explanations.

TROUBLESHOOTING GUIDE

In the event of an error code, unplug the 3MTM AttestTM Auto-reader 390G and plug it back in to initiate the self-diagnostic test. If error code re-occurs, call for repair or replacement.

The LCD display panel will indicate detected malfunctions by displaying a caution or error code under affected Bl wells. The audible alarm, if active, sounds and the LCD display backlight flashes to alert the user to all caution (except C1) and error codes. The alarm and backlight can be silenced and extinguished, respectively, by pressing the Buzzer Alarm OFF

button 🛞. Note that disabling the audible alarm does not disable the flashing LCD display backlight. Refer to the following:

| Code/Issue | Problem | Solution | | |
|------------|---|--|--|--|
| C1 | Unit Warm-up Caution | Allow a 30 minute warm-up after 3M [™] Attest [™] Auto-reader 390G is plugged in. (Note: 3M [™] Attest [™] Deside a 27% / 200) | | |
| | Incubation block not at temperature. | Rapid Readout BI readings are disabled until incubator block reaches 37°C +/- 2°C). | | |
| | BI Removed from Well Caution | Replace 3M [™] Attest [™] Rapid Readout BI in proper well within 10 seconds to prevent loss of collected data. | | |
| C2 | 3M [™] Attest [™] Rapid Readout BI has been removed before incubation is complete. | | | |
| C4 | Ambient Light Caution | Move 3M [™] Attest [™] Auto-reader 390G to reduced ambient light conditions. | | |
| | Temperature Control Error | Unplug the unit and plug it back in to clear error. | | |
| E1 | This error will occur if system is no longer able to control the temperature of the incubator block ($37^{\circ}C +/- 2^{\circ}C$). | If error doesn't clear, call for repair or replacement. | | |
| | Memory Error | Unplug the unit and plug it back in to clear error. | | |
| E3 | 3M [™] Attest [™] Auto-reader 390G unable to save/read data from memory. | If error doesn't clear, call for repair or replacement. | | |
| E7 | Communications Error | Call for repair or replacement. | | |
| C/ | This error will occur if internal communications have failed. | | | |
| | LED Error | Unplug the unit and plug it back in to clear error. | | |
| E8 | This error occurs for a specific well if the system detects | If error doesn't clear, call for repair or replacement. Do not use affected incubation well. | | |
| | that a UV LED or Optics Detection circuit is not working. BI Inserted Incorrectly Error | | | |
| E11 | Incubation time remaining will not display and fluorescent | Ensure BI is designed to be incubated and read in the 3M [™] Attest [™] Auto-reader 390G. | | |
| | readings are not taken. | Ensure BI is fully inserted into incubation well. | | |
| | Power Failure Error | | | |
| E12 | Power to Auto-reader was off for too long to provide valid result for affected BI(s). | Ensure power supply connection to Auto-reader is secure. | | |
| E14 | Ambient Light Error (occupied well) | Rely on optional visual pH color change result for BI in affected well. Move 3M [™] Attest [™] | | |
| | Fluorescent result will not display. | Auto-reader 390G to reduced ambient light conditions to avoid future occurrences. | | |
| Other | Unwanted alarm sounds when positive BI detected. | Disable alarm; refer to 3M™ Attest™ Auto-reader 390G Configuration section for instructions. | | |
| | Alarm Sounds | Replace 3M [™] Attest [™] Rapid Readout Biological Indicator in incubation/reader well within 10 seconds | | |
| Other | 3M [™] Attest [™] Rapid Readout Biological Indicator has been removed from incubation/reader well prematurely. | to prevent loss of data collected. | | |
| Other | LCD panel does not display properly. | Unplug the unit and plug it back in. If problem persists call for repair or replacement. | | |
| Other | Negative Control Vial | Ensure BI cap is closed, and glass ampoule is crushed. Tap BI until media flows to and wets spore strip | | |
| | BI not properly activated/ media did not contact spore strip. | at bottom of BI. | | |
| Other | Negative Control Vial | Check process indicator on BI label. Use a non-sterilized vial as a control. | | |
| oulor | Control vial was sterilized. | | | |
| Other | Unexplained Positive Bl | Do not place tape or labels on vial. | | |
| | Adhesive residue on vial. | | | |
| 0 | Unexplained Positive BI | | | |
| Other | Test vial is absorbing fluorescent residue from a chemical indicator or tape. | Place the vial so it does not come in direct contact with chemical indicators or tape. | | |
| Other | 3M [™] Attest [™] Auto-reader 390G will not enter | | | |
| | Configuration mode. | On 3M [™] Attest [™] Auto-reader 390G Web App Configuration Page, go to Pushbutton Configuration and select the Enable radio button. Save changes to begin using new setting. | | |
| | Pushbutton Configuration may be disabled on 3M [™] Attest [™] Auto-reader 390G Web App. | onor are transferration battern, ouve onanges to begin doing new setting. | | |
| Other | 3M [™] Attest [™] Auto-reader 390G LCD display flashes and asterisks (***) and/or E11 and/or C4 codes appear on | Move 3M™ Attest™ Auto-reader 390G away from sunlight or sources of incandescent light. | | |

OPTIONAL 3M™ ATTEST™ AUTO-READER 390G WEB APP

Web Browser Requirements

The Web Interface is designed to be viewed in Internet Explorer 8.0 or higher. Earlier versions of Internet Explorer or other browsers may result in some web pages being displayed in a less-than-optimum manner. For best results, switching to Internet Explorer 8.0 or higher is recommended. For full functionality, the use of an HTML5 compliant browser with JavaScript enabled is recommended.

Connecting to the 3M[™] Attest[™] Auto-reader 390G Web App

To use the 3M[™] Attest[™] Auto-reader 390G Web App, the 3M[™] Attest[™] 390G Auto-reader must be connected to the facility network using the supplied Ethernet cable. Consult with your facility IT personnel for assistance with network connectivity. Users may connect to the 3M[™] Attest[™] Auto-reader 390G Web App using a URL based upon either the 3M[™] Attest[™] Auto-reader 390G serial number or the IP Address. To view the 3M[™] Attest[™] Auto-reader 390G Web App from a wireless device such as a mobile hand-held device or a computer on a sub-net different from that to which the 3M[™] Attest[™] Auto-reader 390G is connected, use the IP Address URL.

Note: To access the 3M[™] Attest[™] Auto-reader 390G Web App within a secure network, the PC or mobile device must have access to the secure network; options include connecting via a network Ethernet cable, signing in to the facility's wireless network, or connecting via a virtual private network (VPN).

A. Serial number URL

- 1. Connect the supplied Ethernet cable from the 3M[™] Attest[™] Auto-reader 390G to an Ethernet jack.
- Depress the ¹ button once to display the 3M[™] Attest[™] Auto-reader 390G 6-digit serial number on the left side of the top row of text on the LCD display.
- Enter http://attestxxxxx where xxxxxx represents the unit's serial number (e.g., http:// attest401008) from Step 2 in PC web browser address bar and press Go.
- 3M[™] Attest[™] Auto-reader 390G Web App Status page will display on PC. For future ease of use, add this page to your web browser "Favorites."

B. IP Address URL

The 3M[™] Attest[™] Auto-reader 390G Web App may also be accessed using either a dynamic or static IP address.

1. Dynamic IP Address

A dynamic IP address is assigned when the Ethernet cable is connected from the $3M^{TM}$ AttestTM Auto-reader 390G to a live Ethernet jack.

Press and release the [€] button twice to display the 3M[™] Attest[™] Auto-reader 390G's dynamic IP address. Enter http://IPaddress (e.g. http://123.45.678.90) in the web browser address bar of the PC or mobile hand-held device and press Enter. The 3M[™] Attest[™] Auto-reader 390G Web App Status page will display.

2. Static IP address

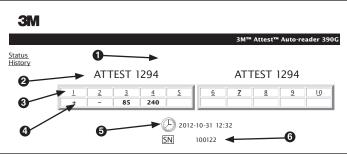
Some facility IT personnel may require devices connecting to the network to use a Static IP address. If this is the case at your facility, contact the IT department to request a Static IP address.

Record the static IP address provided by your facility IT department here: ______. You may wish to label the Ethernet jack with the assigned address. Enter http://StaticIPaddress (e.g. http://111.22.333.44) in the web browser address bar on your PC or mobile hand-held device and press Enter. The 3M[™] Attest[™] Auto-reader 390G Web App Status page will display.

About the 3M[™] Attest[™] Auto-reader 390G Web App Pages

The 3M[™] Attest[™] Auto-reader 390G Web App includes four pages:

a) Status page



- 1. User-entered nickname (optional)
- 2. Well Configuration (1-5 and 6-10)
- 3. Well Number
- 4. BI Result/Remaining Incubation Time
- 5. Date and Time
- 6. 3M[™] Attest[™] Auto-reader 390G Serial Number

The Status page provides a real-time representation of the 3M[™] Attest[™] Auto-reader 390G LCD panel display. The current date and time and 3M[™] Attest[™] Auto-reader 390G serial number are also indicated on this page. From this page, the user may navigate to:

- the History page by clicking on <u>History</u> on the left of the screen.
- the Results Detail page by clicking on the well number of an occupied well (i.e., a well that currently has an incubating BI). Clicking on an unoccupied well takes the user to the History page.

b) Results Detail page

| ЗМ | | |
|--|-------------------------|---|
| | | 3M™ Attest™ Auto∙reader 390G Results Detail |
| <u>Status</u> <u>History</u> Print | | |
| | Result | - |
| | Start Time | 2012-10-29 11:08:04 |
| | Well# and Configuration | #3 1294 |
| | 390G Serial Number | 100122 |
| | Control? | |
| | BI Lot# | |
| | Load# | |
| | Sterilizer# | |
| | Technician | |

This page provides an individual record for an incubated BI. For complete documentation, the user may print a hard copy and/or save the record as an electronic file.

Note 1: The top four rows (highlighted in green) are populated automatically by the 3M[™] Attest[™] Auto-reader 390G and cannot be changed by the user. The remaining rows are completed by the user to satisfy the documentation requirements of their facility.

Note 2: The Results Detail page refreshes less frequently that the Status page. Until the BI result is available, the Results Detail page displays remaining minutes of incubation in the results field.

c) History page

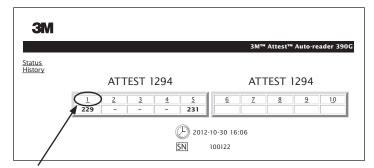
| ЗМ | | | | | |
|-------------|----|-------------------------|---------------------|---------|----------------|
| | | | | 3M™ Att | est™ Auto-read |
| tus tory | ID | Well# and Configuration | Start Time | Result | |
| <u></u> | 1 | #4 1294 | 2012-10-30 12:31:25 | | |
| | 2 | #3 1294 | 2012-10-30 09:57:01 | | |
| | 3 | #3 1294 | 2012-10-30 07:51:51 | + | |
| | 4 | #4 1294 | 2012-10-30 16:15:55 | - | |
| | 5 | #5 1294 | 2012-10-30 16:01:07 | - | |
| | 6 | #1 1294 | 2012-10-30 15:58:18 | + | |
| | Z | #4 1294 | 2012-10-30 11:52:27 | - | |
| | 8 | #4 1294 | 2012-10-30 11:42:26 | C2 | |

The 3M[™] Attest[™] Auto-reader 390G stores results for the last 100 incubated BIs on embedded software. The 3M[™] Attest[™] Auto-reader 390G Web App History page provides a summary of these last 100 results.

d) Configuration page

This page allows the configuration of the 3M[™] Attest[™] Auto-reader 390G's network and language settings from the 3M[™] Attest[™] Auto-reader 390G Web App.

Documenting BI Results using the 3M[™] Attest[™] Auto-reader 390G Web App



1. Open the Results Detail page

After inserting a new 3M[™] Attest[™] Rapid Readout BI in the 3M[™] Attest[™] Auto-reader 390G, it is a best practice to open the 3M[™] Attest[™] Auto-reader 390G Web App Results Detail page for that BI by clicking on the appropriate well number from the Status page.

 Enter the specific information for that BI (e.g., BI Lot #, sterilizer/load number, Technician name, etc.) in the provided editable fields. Use the Notes section to capture information not prescribed in the provided row titles; for example, you may wish to use this field to record load items.

| ЗМ | | |
|---------------------------------|-------------------------|---|
| | | 3M™ Attest™ Auto∙reader 390G Results De |
| <u>tatus</u> listory rint | | |
| | Result | 223 |
| | Start Time | 2012-10-30 15:58:18 |
| | Well# and Configuration | #1 1294 |
| | 390G Serial Number | 100122 |
| | Control? | No |
| | BI Lot# | 2014-11AD |
| | Load# | 1 |
| | Sterilizer# | 2 |
| | Technician | sdf |

- 3. The entered information is **saved** automatically to temporary web browser storage on the user's PC every 60 seconds, or by leaving the Results Details page.
- 4. **Print/File.** Once the BI result is available, print or file the Results Detail page to create a record. The page may be physically printed and/or saved as an electronic file.

Important! Data is only stored for the last 100 incubated BIs.

Embedded software in the 3M[™] Attest[™] Auto-reader 390G saves the data from the auto-populated (i.e., green highlighted) fields. The application relies on the temporary storage in the user's web browser to save the data in the user-populated fields. In both cases, data is only stored for the last 100 records, i.e., the 101st incubated BI will erase the information saved for the 1st incubated BI. To retain the Results Detail information for future reference it is best practice to print the page or save to an electronic file as soon as the BI result is available.

Using the BI History Page

| N | | | |
|----|-------------------------|---------------------|-------|
| | | | 3M™ / |
| ID | Well# and Configuration | Start Time | Resul |
| 1 | #4 1294 | 2012-10-30 12:31:25 | |
| 2 | #3 1294 | 2012-10-30 09:57:01 | |
| 3 | #3 1294 | 2012-10-30 07:51:51 | + |
| | 4 1294 | 2012-10-30 16:15:55 | - |
| 5 | #5 1294 | 2012-10-30 16:01:07 | - |
| 6 | #1 1294 | 2012-10-30 15:58:18 | + |
| Z | #4 1294 | 2012-10-30 11:52:27 | - |
| 8 | #4 1294 | 2012-10-30 11:42:26 | C2 |

To view or print an individual record, click on the ID number of the desired record to navigate to the Results Detail page for that BI.

Note 1: Column 1, "ID" is the assigned ID number with ID 1 representing the newest record and ID 100 representing the oldest record. For convenience, all columns are sortable; to help find a particular record, simply click once on the column heading to sort in ascending order and click a second time to reverse the order.

Note 2: The History page refreshes less frequently than the Status page. Until the BI result is available, the History page displays ••• in the Results column indicating incubation is still in-process.

Using the Configuration Page

Certain set-up and configuration options are available on the password-protected 3MTM AttestTM Auto-reader 390G Web App Configuration page. Ideally, the 3MTM AttestTM Auto-reader 390G should be empty (i.e., have no incubating BIs) when it is reconfigured. Navigate to the Configuration page by entering either:

1) http://attestxxxxx/protect/config.htm (where xxxxxx is the 6-digit unit serial number), or

2) http://xxx.xx.xx/protect/config.htm (where xxx.xx.xxx is the IP address)

in the web browser address bar and pressing Go or Enter. A security screen will appear. Fill in the fields as follows:

User name: manager

Password: Attest

and press OK.

Click on the desired radio buttons to change settings.

| Language | Selected setting indicates language in which text on 3M [™] Attest [™] Auto-reader 390G Web App pages will appear on the PC/mobile device screen. | | |
|----------------------------------|--|--|--|
| | Selecting Enable ⊙ allows the user to configure the 3M [™] Attest [™] Auto-reader 390G from the buttons on the unit itself. | | |
| Pushbutton Configuration | Selecting Disable \odot prevents the user from being able to configure the 3M TM Attest TM Auto-reader 390G from the buttons on the unit itself. | | |
| Duzzor Configuration | Selecting Enable ⊙ enables the audible alarm. The speaker icon will appear on the 3M [™] Attest [™] Auto-reader 390G LCD panel. | | |
| Buzzer Configuration | Selecting Disable Selecting Disables the audible alarm. The speaker icon will disappear from the 3M TM Attest TM Auto-reader 390G LCD panel. | | |
| Attest Auto-reader 390G Nickname | Naming the 3M [™] Attest [™] Auto-reader 390G may be useful in facilities with multiple units. The assigned nickname will appear on the 3M [™] Attest [™] Auto-reader 390G Web App Status page. | | |
| Enable DHCP | Default: Setting is checked indicating the Web App will use the Dynamic IP address automatically assigned when the 3M [™] Attest [™] Auto-reader 390G is connected to the network. Remove the check if you wish to use a Static IP address assigned by your facility IT. | | |
| IP Address | Enter Static IP address assigned by IT. | | |
| Gateway | Enter Gateway. | | |
| Subnet Mask | Enter Subnet Mask. | | |
| Primary DNS | Enter Primary DNS. | | |
| Use Computer Time | Check this box if you wish to set the clock on-board the 3M [™] Attest [™] Auto-reader 390G using the computer's clock. | | |
| Attest Auto-reader 390G Time | Alternatively, leave the Use Computer Time box unchecked and complete the date and time boxes to set the 3M [™] Attest [™] Auto-reader 390G clock. | | |
| | | | |

After changing desired settings, click on Save Config button to save your changes. A new screen confirming the settings were successfully changed appears.

TROUBLESHOOTING THE 3M[™] ATTEST[™] AUTO-READER 390G WEB APP

| Issue | Problem | Solution |
|--|---|---|
| | | Ensure 3M [™] Attest [™] Auto-reader 390G Ethernet cable is connected to a live jack and that connection to 3M [™] Attest [™] Auto-reader 390G is secure. |
| Unable to access 3M [™] Attest [™] Auto-reader 390G Web App on | 3M [™] Attest [™] Auto-reader 390G and/or | Ensure computer is connected to network. |
| networked computer | computer not connected to network. | If failure is with connection attempted using 3M [™] Attest [™] Auto-reader 390G serial number URL, try connecting using IP address URL. |
| | | Contact facility IT or 3M if problem persists. |
| Unable to access 3M [™] Attest [™] | 3M [™] Attest [™] Auto-reader 390G not connected to network. | Ensure 3M [™] Attest [™] Auto-reader 390G Ethernet cable is connected to a live jack and that connection to 3M [™] Attest [™] Auto-reader 390G is secure. |
| Auto-reader 390G Web App on mobile device | For security reasons, facility firewall may prevent mobile devices not connected to the facility network from connecting to secure IP addresses. | Contact facility IT for their recommendation on connecting to the secure network. Solutions may include enabling Wi-Fi on the mobile device and signing into the facility network or connecting to the facility virtual private network (VPN) on the mobile device. |
| Data entered by user on Results Detail page disappears | User entered data is written to temporary web browser storage. Browser may have cleared data. | Set web browser to accept (allow or enable) cookies. As a best practice, print or save Results Detail record as soon as BI result is final. |
| BI result displayed on 3M [™] Attest [™] Auto-reader 390G LCD panel does not appear on Results Detail page | The Results Detail page has not refreshed yet. | Use your browser to refresh the Results Detail page, or wait up to 60 seconds for the page to automatically refresh. |
| Results Detail page will not open from the Status page | The Results Detail page only opens from the Status page for occupied 3M [™] Attest [™] Auto-reader 390G wells. | Do not attempt to navigate to the Results Detail page from unoccupied wells on the Status page. |

REPAIR AND REPLACEMENT

In the U.S.A., 3M[™] Attest[™] Auto-reader 390Gs must be repaired at: **3M Health Care Service Center** Suite 200, Bldg. 502 3350 Granada Avenue North Oakdale, MN 55128 1-800-292-6298 Fax: 1-800-770-8016

Outside of the U.S.A., contact your local 3M Subsidiary.

If you have questions, call our Customer Service number: 1-800-292-6298.

Made in U.S.A. by

M Health Care

2510 Conway Ave St. Paul, MN 55144 1-800-228-3957 www.3M.com/healthcare

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